IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA

GENESIS HEALTH CARE INC., Plaintiff, v. XAVIER BECERRA, as Secretary of the United States Department of Health and Human Services, CAROLE JOHNSON, as Administrator of the Health Resources and Services Administration, and EMEKA EGWIM, as Lieutenant Commander in the United States Public Health Service and Director of the Office of Pharmacy Affairs in the Health Resources and Services Administration, Defendants.	Case No. 4:19-cv-01531-RBH

BRIEF OF THE JANSSEN PHARMACEUTICAL COMPANIES AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

William A. Sarraille (D.C. Bar No. 431872)
Pro hac vice motion pending
Paul J. Zidlicky (D.C. Bar No. 450196)
Pro hac vice motion pending
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005
Telephone: (202) 736-8000
Facsimile: (202) 736-8711
wsarraille@sidley.com
pzidlicky@sidley.com

Joel H. Smith
Bowman and Brooke LLP
1441 Main Street,
Suite 1200
Columbia, SC 29201-2897
Telephone: (803) 726-74220
Facsimile: (803) 726-7421
joel.smith@bowmanandbrooke.com

Counsel for The Janssen Pharmaceutical Companies

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Civil Procedure 7.1, Janssen Pharmaceuticals, Inc., Janssen Biotech, Inc., Janssen Products, LP, Patriot Pharmaceuticals, LLC, and Actelion Pharmaceuticals US, Inc., are each wholly owned subsidiaries of Johnson & Johnson. Johnson & Johnson is a publicly traded corporation that has no parent company, and no publicly held company owns 10 percent or more of its stock.

IDENTITY AND INTEREST OF *AMICI CURIAE*[1]

The Janssen Pharmaceutical Companies ("Janssen")[2] are participants in the 340B program and are wholly owned subsidiaries of Johnson & Johnson ("J&J"), the world's largest manufacturer of health care products for the pharmaceutical and medical device markets. As a pharmaceutical manufacturer, Janssen is committed to the 340B program, and is proud to participate in it. Unfortunately, despite Janssen's commitment to the program, diversion and duplicate discounts are such a pervasive problem that the 340B program is broken. Too many covered entities, like Genesis Health Care, abuse the program, pursuing profits by systematically engaging in diversion.

Genesis has secured and diverted discounts from the intended recipients to others who, along with Genesis, are wrongfully profiting from the 340B program. This diversion harms the patients Congress designed the program to protect by depriving them of their intended savings, and by increasing the costs to healthcare system, which in turn impairs the ability of manufacturers to innovate life-sustaining treatments and to provide financial support to needy patients. As the procedural history of this case demonstrates, Health Resources & Services Administration's ("HRSA") has not rigorously enforced the letter and intent of the 340B statute to ensure Genesis' compliance, as evidenced by HRSA's abandonment of any enforcement action against Genesis, despite plaintiff's systematic diversion of 340B drugs. HRSA's failings in this case mirror its lax

[1] No party's counsel authored this brief in whole or in part, and no party, its counsel, or any other person—other than Janssen or its counsel—contributed money intended to fund preparation or submission of this brief. *See* Fed. R. App. P. 29(a)(4)(E). The Federal Defendants have consented to the filing of this amicus brief; Plaintiff has not consented to the filing of this brief.

[2] The Janssen Pharmaceutical Companies consist of Janssen Pharmaceuticals, Inc., Janssen Biotech, Inc., Janssen Products, LP, Patriot Pharmaceuticals, LLC, and Actelion Pharmaceuticals US, Inc.

enforcement generally, which has allowed widespread abuse and exploitation of the 340B program, and the pervasive diversion of discounts away from the intended recipients.

Janssen provides billions of dollars each year to 340B covered entities. All too often, these funds are siphoned off to third parties, such as large, for-profit contract pharmacies, third-party "administrators," and "consultants" that push violations of law as "profit maximizing" strategies.

As a consequence, few 340B discounts are actually used to reduce patient co-payments at the pharmacy counter.[3] Instead, many of those dollars are ultimately paid to multi-billion dollar commercial pharmacies and for-profit "administrators" and "consultants."[4] The government has consistently failed to address pervasive diversion and duplicate discounts – clear violations of law. A critical and growing source of diversion are "definitions" of the term "patient" that are, in reality, systematic means to engage in widespread diversion of 340B discounted drugs. For years, Janssen has tried (unsuccessfully) to address this problem within the 340B Program—a problem that the government has repeatedly acknowledged, but failed to address in any meaningful way.

Genesis' unbounded interpretation of "patient" is contrary to the law and would improperly expand a program already suffering from the abuses described above. The statutory scheme originated to restore voluntary discounts that manufacturers, like Janssen, had historically provided to a limited number of safety net providers that offered direct clinical care to needy patients.

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[3] *See* Gov't Accountability Off. ("GAO"), GAO-18-480, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* 31 (June 2018), https://www.gao.gov/assets/700/692697.pdf; Off. of Inspector Gen., HHS, Memorandum Report, *Contract Pharmacy Arrangements in the 340B Program, OEI-05-13-00431*, at 2 (Feb. 4, 2014), https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf.

[4] *See, e.g.*, Ltr. from Adam J. Fein, Drug Channels Inst., to Hon. Lamar Alexander & Hon. Greg Walden, at 1-2 (Oct. 30, 2020), http://drugchannelsinstitute.com/files/AdamFein-DrugChannels-340B-30Oct2020.pdf (noting that "there is … zero transparency around the profits earned by billion-dollar public companies that dominate 340B pharmacy networks" and that "occur at the expense of needy and uninsured patients").

Congress' enactment of the Medicaid Drug Rebate Program had forced manufacturers to discontinue those discounts, however. After years of neglect and mismanagement by HRSA, the original, limited purpose of the program has now been lost. The 340B program has been improperly stretched far beyond its original intent, largely as a consequence of diversion and duplicate discounts, into the second largest federal drug program - without reducing patients' drug costs.

If Genesis were successful here in advancing an utterly contentless "definition" that effectively would allow each covered entity to claim any person as their "patient" no matter how long ago that person was seen for a service and no matter how unrelated that service was to the drug for which a 340B discount is claimed—the program will collapse. Even those covered entities now applying a meaningful patient definition will adopt the Genesis policy. With 13,000 covered entities and more than 30,000 contract pharmacies participating in the program, a court ruling supporting Genesis' patient "definition" would add billions of dollars of cost to the program. This enormous additional expansion of the 340B program would threaten manufacturers' ability to maintain both their current level of funding for the development of life-sustaining treatments and financial support to needy patients to provide for reduced co-payments or free drugs. That threat is all the more alarming, because, as Genesis' own example demonstrates, profits obtained by 340B covered entities are often not leading to reductions in patients' drug costs.

Janssen seeks to assist the Court by providing additional information on the 340B statute, its history, and how the 340B program has been abused by covered entities, including Genesis. Janssen also addresses the timeliness of Genesis' lawsuit, the plain language meaning of the statute, and the absurd results that would flow from the adoption of Genesis' misinterpretation of the statute. Janssen submits this amicus brief in support of Defendants because it asks the Court to

reject the relief sought by Genesis. Nevertheless, although Janssen agrees with a number of the points advanced by Defendants, Janssen disagrees with some of their statements, and it offers additional points addressed at ensuring that meaningful protections against diversion and duplicate discounts are enforced.

SUMMARY OF ARGUMENT

The 340B program was created for a limited purpose: To restore manufacturer discounts that were voluntarily given to a finite group of safety net providers that offered direct clinical care to needy patients before the enactment of the Medicaid Rebate Program made that impossible. Those historic discounts were only provided to the 340B entities responsible for the direct patient care that resulted in the drug prescription. In restoring those discounts through the enactment of the 340B program, Congress carefully balanced that benefit intended to assist patients with a series of safeguards designed to protect manufacturers. Chief among those protections is the prohibition against diversion, which lies at the very heart of the program and is a core requirement for covered entities. *See* 42 U.S.C. § 256b(a)(5)(B). Although Genesis mischaracterizes that central, core provision of the statute as merely a limitation on "reselling" discounted drugs "into the marketplace," Plaintiff's Memorandum in Support of Summary Judgment ("Genesis SJ") at 8 (June 16, 2023), ECF No. 100-1,[5] under the plain language of the statute, the prohibition against diversion is a limitation on any "transfer" of any kind to "a person who is not a patient of the [covered] entity." 42 U.S.C. § 256b(a)(5)(B).

Despite that prohibition, Genesis, in the interest of "maximizing" its profits, has asked this Court to embrace a limitless "definition" of the term "patient." In essence, Genesis asks this Court

[5] *See also id.* ("The term 'patient' as used in Section 256b(a)(5)(B) must be interpreted within the context of the statutory provision's purpose of prohibiting a covered entity from ***reselling the 340B drugs for profit in the open market***.") (emphasis added).

to immunize its violations of law. Genesis attempts to twist a clear prohibition on diversion into an empty clause that would allow Genesis—and every other covered entity—to claim 340B discounts for "patients" they have not seen for any reason for years at a time, never treated for the relevant disease or condition, never issued the relevant prescription, and even where they know that another provider is responsible for the relevant care and prescription. The Court should reject Genesis' unlawful interpretation.

Janssen urges this Court to deny Genesis' motion for summary judgment for the following reasons. **First**, the Court should not even reach the merits because Genesis' claim is a challenge to HRSA's 1996 Guidelines and was, as a consequence, filed more than 16 years ***after*** the applicable six-year statute of limitations ran. **Second**, if this Court does reach the merits, Genesis' proposed patient "definition" is fundamentally inconsistent with the text, structure, and purpose of the statute, both because Genesis (1) refuses to recognize any obligation that, to claim a drug discount, it must have provided services connected to the underlying condition or disease and drug and (2) wrongly, asserts that a past relationship with a former patient is sufficient to meet the statute's requirements. **Third**, this Court should reject Genesis' claims because its entirely limitless "definition" of a "patient" would lead to absurd results and effectively render the diversion prohibition, a key feature of the balance Congress struck in enacting the 340B program, a nullity.

BACKGROUND

A. The Creation of the 340B Program

The 340B program was created for the limited purpose of restoring what had been voluntary discounts extended to a limited set of safety net providers that were providing "direct clinical care" to needy patients. H.R. Rep. No. 102-384, pt. 2 ("House Report"), at 12 (1992). Congress enacted the 340B program in 1992 to address an "unintended consequence" resulting

from the enactment of the Medicaid Drug Rebate Program in 1990. *See* Nicholas C. Fisher, *The 340B Program: A Federal Program in Desperate Need of Revision After Two-and-a-Half Decades of Uncertainty*, 22 J. Health Care L. & Pol'y 25, 30 (2019). Before this, manufacturers "regularly offered discounts to … hospitals and other safety-net providers" on a voluntary basis. *Id.* at 29. Because the Medicaid Drug Rebate Program included a new requirement for manufacturers to report their "Best Price" to calculate Medicaid drug rebates, without excluding these voluntary discounts, *see id.* at 29-30, those discounts resulted almost overnight in significantly higher Medicaid rebates. This so penalized manufacturers, they could no longer offer discounts to safety net providers. *See id.* at 29.

In response, realizing its error, Congress sought to remedy this specific pricing problem through the 340B program. *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967. When enacted, the 340B program restored the discounts that manufacturers had previously extended directly to federally-funded clinics and public hospitals that "serve large numbers of low-income and uninsured patients." House Report at 10-12. Congress specifically stated that it intended that the discounts would be extended to safety net entities providing "direct clinical care" to needy patients. It thus highlighted that recipients of the discounts were expected to be involved directly in the provision of services that gave rise to the need for the drugs. *Id*. At the same time as Congress created the 340B program, it addressed its previous error by amending the Medicaid Drug Rebate Program to exclude those 340B discounts from "Best Price," thereby ensuring the discounts would not lead to higher Medicaid rebates. 106 Stat. at 4962 (codified at 42 U.S.C. § 1396r-8(c)(1)(C)).[6]

[6] As the House Committee report explained, "this exemption [from the Best Price calculation] will remove any disincentive that the Medicaid rebate program creates to discourage manufacturers

Although the legislative history of the 340B program reflects, at one point, a desire to assist covered entities to "stretch scarce resources," Congress created a balanced regime that also prevented diversion and duplicate discounts. Specifically, because there was concern that the substantial size of the 340B discounts would lead to diversion and other attempts to abuse the program, the statute prohibited any "transfer" of a discounted product to anyone, other than a "patient" of the covered entity. *See* 42 U.S.C. § 256b(a)(5)(B). In keeping with Congress' intent to provide discounts only to federally-funded clinics and public hospitals "that provide ***direct clinical care*** to large numbers of uninsured Americans," House Report at 12 (emphasis added), the statute provides that, "[w]ith respect to any covered outpatient drug," an entity "shall not resell or otherwise transfer the drug to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B). The "[w]ith respect to" clause requires that the "covered outpatient drug" be connected to the "entity" and its "patient." This required connection is reinforced in the definition of a "covered drug," which refers to a covered drug "used ***in connection with*** an . . . outpatient ***service provided*** by a hospital." *Id.* § 256b(b)(2)(B) (emphasis added). The covered entity must "use" the drug "in connection with" a service that it actually "provided" to the patient. In other words, the text, purpose, and structure of the statute, read as a whole, show that Congress wanted to ensure that the entities providing "direct clinical care" "[w]ith respect to" a covered drug would have access to the discounts—but no one else.

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from providing substantial voluntary or negotiated discounts to these clinics, programs, and hospitals." *See* House Report at 12.

B. The 340B Program Has Grown Exponentially And That Growth Has Been Significantly Caused By Program Abuse, Including Manipulation Of The Patient Definition.

Although created for a limited purpose and directed to a small number of covered entities, the 340B program has, in the years that followed, grown exponentially. Begun as a "fix" to an issue at the periphery of the Medicaid Rebate program, the 340B program now is **larger** than the Medicaid program. *See* Nicole Longo, *340B Program Remains Second Largest Federal Drug Program, Yet Little Solid Evidence of Benefits to Patients*, PhRMA (June 30, 2022), https://phrma.org/Blog/340b-program-remains-second-largest-federal-drug-program-yet-little-solid-evidence-of-benefits-to-patient. The 340B program in 2020 involved $38 billion in discounts *See* Longo, *supra*. In 2022, Janssen and other J&J companies paid $6.2 billion in 340B discounts and $3.8 billion in Medicaid rebates. Janssen, *The 2022 Janssen U.S. Pricing Transparency Brief* at 1 (2023) ("J&J Transparency Report"), https://transparencyreport.janssen.com/_document/2022-janssen-transparency-report-pdf?id=00000188-267e-d95e-abca-7e7e58750000.[7] The government and others have expressed

[7] The now fundamentally inverted relationship between the Medicaid and 340B program demonstrates that, at this point, the 340B program constitutes an unconstitutional taking. *E.g., Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013); *Dolan v. City of Tigard*, 512 U.S. 374, 385 (1994). The 340B program now forces manufacturers, like Janssen, to provide billions of dollars in drugs, without compensation, to private parties, without any compensation. Although the government contends that manufacturers "voluntarily" participate in the 340B program, the reality is that the "bargain" of Medicaid coverage in exchange for 340B participation has fundamentally and irrevocably changed as a consequence of the massive growth in the 340B program. The 340B program imposes a disproportionate burden on manufacturer participation in the Medicaid program. But with manufacturers being so dependent on the Medicaid program, they are coerced to continue to participate in it. *See Koontz*, 570 U.S. at 606 ("[T]he unconstitutional conditions doctrine forbids burdening the Constitution's enumerated rights by coercively withholding benefits from those who exercise them.") This substantial Taking Clause problem would grow substantially worse if Genesis' virtually limitless patient "definition" were adopted by the Court. Accordingly, the doctrine of constitutional avoidance supports the rejection of Genesis' definition of "patient." *E.g.*, *Edward J. DeBartolo Corp. v. Florida Gulf Coast Bldg. & Constr. Trades Council*, 485 U. S. 568, 575 (1988).

significant concerns that the use of contract pharmacies brings substantial increased risk of diversion and duplicate discounts. *See* GAO, GAO 11-836, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* 28 (Sept. 2011), https://www.gao.gov/assets/gao-11-836.pdf; GAO, GAO-18-480, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* 44 (June 2018), https://www.gao.gov/assets/gao-18-480.pdf.

The government and others have candidly acknowledged that the explosive growth of the 340B program has been caused to a significant degree by violations of the 340B program by covered entities. *See, e.g.*, GAO 11-836, *Manufacturer Discounts in the 340B Program Offer Benefits*, *supra*, at 28 (noting that the "[i]ncreased use of the 340B program by contract pharmacies and hospitals may result in a greater risk of drug diversion, further heightening concerns about HRSA's reliance on participants' self-policing to oversee the program"); GAO-18-480, *Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, *supra*, at 44 (emphasis added) (concluding that "[t]he identified noncompliance at contract pharmacies raises questions about the effectiveness of covered entities' current oversight practices") (emphasis added); Adam J. Fein, Drug Channels, *The 340B Program Climbed to $44 Billion in 2021—With Hospitals Grabbing Most of the Money* (Aug. 15, 2022), https://www.drugchannels.net/2022/08/the-340b-program-climbed-to-44-billion.html.

Manipulation of the patient definition and resulting diversion is one of the most significant—and growing—threats to the program. HRSA, GAO, and others have repeatedly expressed concerns about the threat of diversion and abusive patient "definitions." *See, e.g.*, HRSA, Notice, *Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Definition of "Patient"*, 72 Fed. Reg. 1543, 1544 (Jan. 12, 2007) ("[I]t is possible that some 340B covered

entities may have interpreted the definition too broadly, resulting in the potential for diversion of medications purchased under the 340B Program. Therefore, HRSA finds it necessary to issue this Notice, and to include several examples that further illustrate the guidance."); *id.* at 1545–1546 (discussing "examples describ[ing] the issues that HRSA has identified as problematic and the relationships that do not meet the definition of 'patient' for purposes of compliance with the 340B Program guidelines"); GAO, GAO 11-836, *Manufacturer Discounts in the 340B Program Offer Benefits*, *supra*, at 28 ("Operating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies."). A recent 340B conference acknowledged that various covered entities take the extreme position that "everybody we have ever treated at any point is our patient." 340B Insider, Cloudmed, *Legal Considerations and Compliance for 340B Program Optimization*, https://www.cloudmed.com/resource/340b-insider-december-2022/ (last visited Aug. 3, 2023).

C. Genesis' Participation in the 340B Program Has Raised Significant Concerns.

Genesis bears all the hallmarks of a covered entity abusing the 340B program. Its CEO receives excessive compensation. Genesis maintains a large "contract pharmacy" network that extends thousands of miles from its purported service area. Its profits are disproportionately the product of 340B transactions and far exceed its year-to-year financial needs. Genesis' policy to forgive co-payment costs for the financially needy covers only a fraction of the estimated population in the service area, despite its enormous financial reserves. And, as detailed in the government's audit, Genesis is engaged in systematic diversion.

Genesis' leadership has been the subject of criticism. As the *Washington Post* revealed in an investigative report, Genesis' CEO, although the leader of a not-for-profit receiving federal grants to serve vulnerable, underinsured, and at-risk patients, was paid nearly $877,000 in salary and bonuses in 2021 alone. *See* Phil Galewitz & Bran Sable-Smith, *For a Few Community Health*

Centers, Serving the Poor Brings Big Surpluses, Wash. Post, Aug. 12, 2022. That compensation is nearly four times the industry average. *Id*.[8]

Although Genesis presents itself as serving only the Piedmont area, it has a dazzling array of "contract pharmacy" relationships. As of July 2023, it had no less than 130 active contract pharmacies. *See* HRSA Off. of Pharm. Affairs 340B OPAIS Database, https://340bopais.hrsa.gov/ContractPharmacySearch/False/000071324.[9] In addition, it has previously had an additional 230 such relationships. Its current relationships are located, among other places, in Arizona, California, Delaware, Hawaii, Illinois, Indiana, Kansas, Louisiana, Massachusetts, Michigan, Missouri, New Jersey, Nevada, Ohio, Pennsylvania, Tennessee, and Texas. Genesis' vast network of contract pharmacies stretches hundreds, even thousands, of miles from its stated "service area." It is so large and so geographically dispersed that it appears to reflect a plan to "capture" former patients and claim their drug use no matter how far away they may reside. Such extensive contract pharmacy networks necessarily pose substantially increased risk of diversion, duplicate discounts, and other program abuse.

Further, the revenue and "surplus" profits that Genesis generates from the 340B program are enormous. As the *Washington Post* has reported, 340B sales allowed Genesis, a not-for-profit entity, to record "a $19 million surplus on $52 million in revenue," in a single year, according to its own audited financial statements. Galewitz, *supra*. Indeed, "***[m]ost*** of Genesis's revenue comes from the 340B program." *Id*. (emphasis added.) In one year analyzed by *The Washington Post*,

[8] Such excessive compensation can constitute a violation of the prohibitions on private benefit and private inurement that apply to tax-exempt organizations, like Genesis, and its "insiders." BoardSource, *Private Benefit, Private Inurement, and Self-Dealing* (June 8, 2016), https://boardsource.org/resources/private-benefit-private-inurement-self-dealing/.

[9] To obtain this figure from HRSA's database for contract pharmacies, enter Genesis' 340B ID (CHC28973) into the "340B ID" field of the database search page.

"[m]ore than $25 million" came from the "sale of drugs." This enormous profit generation is not an anomaly. In the period from 2018 to 2021, Genesis' "surpluses … topped ***35 percent***" for "***four***[] consecutive years." *Id*. (emphasis added). As the *Washington Post* observed, "the industry average is ***5 percent***," meaning that Genesis generates surpluses that are seven times the industry average. *Id*. (emphasis added). Any not for profit with such "a high margin raises questions about where did the surplus go and its tax-exempt status," just as the CEO's unusually high compensation at a not-for-profit entity raises serious private inurement and private benefit issues. *Id*. (internal quotation marks omitted).[10]

Indeed, as demonstrated by HRSA's audit, Genesis produces these large drug revenues using a system that is premised on diversion. As the government points out, the audit followed complaints from two different South Carolina health centers and federal grantees.[11] In a remarkable sign of the extent of the problem, Genesis was unable to produce adequate documentation of a purported "provider-patient relationship" for both in-house pharmacy and contract pharmacy dispenses of drugs. Gov't Br. at 5-6. In a number of cases, Genesis was not able to show that it had provided healthcare services from a healthcare professional with even a loose relationship with Genesis. *Id*. at 6. In a particularly disturbing finding, Genesis added "note[s]"

[10] As a federally qualified health care center receiving federal grants, Genesis is obligated to "prepare[] a … schedule of discounts" to be applied to the payment "of its services" and to adjust those discounts "on the basis of the patient's ability to pay." 42 U.S.C. § 254b(k)(3)(G)(i). Despite this obligation and Genesis' enormous surpluses, our analysis of Genesis' stated "sliding scale" reveals that 68% of the South Carolina population would, in fact, be required, in a household size of just two people, to pay full price for all services that they receive. Significantly, Genesis does not disclose the total amount of any discounts it provides to patients at the pharmacy counter. That omission is telling.

[11] *See* Defendants' Combined Brief in Opposition to Plaintiff's Motion for Summary Judgment and In Support of Defendants' Cross-Motion for Summary Judgment ("Gov't Br.") at 5 (July 28, 2023), ECF No. 101. The fact that other South Carolina health care entities made complaints against Genesis underscores that abuse of a patient definition harms stakeholders in South Carolina other than drug manufacturers.

regarding individuals' purported "visit history after filling prescriptions," which raises questions about the integrity, accuracy, and good faith of Genesis' record-keeping. *Id*. The examples reported by Defendants reflect precisely the kinds of diversion that are the inevitable consequence of Genesis' free-form definition of "patient." *Id*. Those included situations where Genesis failed to document it had provided any relevant care for the condition at issue or had initiated the prescription. *Id*. Although Genesis incorrectly represented to HRSA that it had met HRSA's patient definition, it has now, belatedly, abandoned any real pretense that it ever did so. *See id.* at 13.

Despite these concerns, since 2019, HRSA has "not issue[d] diversion findings for dispensing 340B drugs to ineligible individuals." GAO, GAO-21-107, *Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements* 15 (Dec. 2020), https://www.gao.gov/assets/gao-21-107.pdf. Further, HRSA has so burdened manufacturers wanting to audit covered entities that manufacturers must have proof of diversion or other misconduct before initiating such an audit. *See* HRSA, Final Notice, *Manufacturer Audit Guidelines and Dispute Resolution Process 0905-ZA-19*, 61 Fed. Reg. 65,406, 65,410 (Dec. 12, 1996). Even where manufacturers meet this standard, HRSA imposes requirements for the conduct of audits that are so difficult and expensive, they are almost impossible to satisfy as a practical matter. In this way, covered entities that violate the law are not required to answer for these violations, and manufacturers are denied the protections promised to them by statute.

ARGUMENT

I. GENESIS' CHALLENGE TO HRSA'S DEFINITION OF "PATIENT" UNDER THE 340B PROGRAM SHOULD BE DISMISSED AS UNTIMELY.

The Fourth Circuit has explained that the "real issue" remaining in this case is "whether the 1996 Guidelines," which provide HRSA's existing definition of "patient" under the 340B statute, "are inconsistent with the statute." *Genesis Healthcare, Inc. v. Becerra*, 39 F.4th 253, 261

(4th Cir. 2022). According to Genesis, "[a]ny and all interpretations or guidance of HRSA in contradiction of the plain wording of 42 U.S.C. § 256b(a)(5)(B) are unlawful and unenforceable as a matter of law." *See* Genesis SJ at 20. Genesis, however, may not challenge the 1996 Guidelines because that challenge falls well outside the six-year statute of limitations for claims under the Administrative Procedure Act. *See* 28 U.S.C. 2401(a); *Jersey Heights Neighborhood Ass'n v. Glendening*, 174 F.3d 180, 186 (1999) (challenge to agency action under the APA is subject to six-year statute of limitation).[12] Indeed, Genesis' challenge comes more than sixteen years too late.

A. Genesis' Challenge to the 1996 Guidelines Is Untimely Under the Six-Year Statute of Limitations.

Genesis argues that HRSA's "definitions of the term 'patient' are not enforceable." Genesis SJ at 11 (cleaned up). Specifically, Genesis challenges the "three-pronged 'definition'" of "patient" contained in HRSA's 1996 Guidance. *Id.* at 11-12; HRSA, Final Notice, *Notice Regarding Section 602 of the Veterans Healthcare Act of 1992 Patient and Entity Eligibility*, 61 Fed. Reg. 55,156, 55,157-58 (Oct. 24, 1996).[13] As the Fourth Circuit has explained, HRSA's "1996 Guidelines definition of 'patient'" formed the basis for "Genesis Healthcare's lawsuit," *Genesis*, 39 F.4th at 260, and "[t]he real issue" that remains in this case is "whether the 1996 Guidelines are inconsistent with the statute, as [Genesis] has alleged and with respect to which [Genesis] sought a declaratory judgment." *Id.* at 261.

But Genesis' challenge to the 1996 Guidelines defining the term "patient" is untimely. Under 28 U.S.C. § 2401(a), "every civil action commenced against the United States shall be

[12] *See* Gov't Br. at 14 n.6 ("[A]ny challenge to the 1996 guidelines themselves is time-barred."); Defendants' Answer to Amended Verified Petition for Judicial Review at 11 (Sept. 22, 2022), ECF No. 66 ("Some or all of the Plaintiff's claims are barred by the statute of limitations.").

[13] Genesis likewise disagrees with the guidance issued by HRSA in 2015 to identify "Individuals Eligible to Receive 340B Drugs," but acknowledges that HRSA "officially withdr[ew]" the 2015

barred unless the complaint is filed within six years after the right of action first accrues." *Id.* Further, a cause of action accrues under Section 2401(a) "at the time of 'final agency action.'" *Hire Order Ltd. v. Marianos*, 698 F.3d 168, 170 (4th Cir. 2012) ("When, as here, plaintiffs bring a facial challenge to an agency ruling . . . the limitations period begins to run when the agency publishes the regulation") (citation omitted); *Outdoor Amusement Bus. Ass'n, Inc. v. Dep't of Homeland Sec.*, 983 F.3d 671, 681-82 (4th Cir. 2020) (same); *accord Harris v. FAA*, 353 F.3d 1006, 1010 (D.C. Cir. 2004) ("The right of action first accrues on the date of the final agency action."); *see also North Dakota Retail Ass'n v. Board of Governors of the Fed. Rsrv. Sys.*, 55 F.4th 634, 640-41 (8th Cir. 2022) (citing cases explaining that a facial challenge to agency action accrues upon publication).

These well-established principles compel dismissal of Genesis' lawsuit. Genesis' claim here is a challenge to the definition of "patient" in 1996 Guidelines. *See* Genesis SJ at 11-13 (challenging HRSA's "Publications of definitions of the Term 'Patient'" as "Not Enforceable"); *id.* at 14-15 (arguing that "HRSA Does Not Have Authority to Interpret the Meaning of the Word 'Patient' in § 256b(a)(5)(B) of the 340B Statute"). Under Fourth Circuit law, a claim that an agency rule was "improperly issued" begins to run when the standard is published. *See Outdoor Amusement*, 983 F.3d at 681-82. Genesis' challenge to the 1996 Guidelines thus is untimely because Genesis filed its lawsuit in 2018, more than ***sixteen years*** too late.

B. The Fourth Circuit's Prior Decision Supports The Conclusion That Genesis' Complaint Should Be Dismissed.

The Fourth Circuit's prior ruling supports dismissal for Genesis' failure to act within the statute of limitations. In its decision, the Fourth Circuit stated that "Genesis Healthcare's challenge

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Guidance "on January 30, 2017" and that the 2015 Guidance "has not been re-issued." Genesis SJ at 17. Accordingly, the 2015 Guidance is irrelevant to this case.

to the 1996 Guidelines was also *likely a challenge to final agency action*." 39 F.4th at 262 (emphasis added). Specifically, the Court of Appeals, quoting the Supreme Court, explained that an agency's action "that 'give[s] notice of how the [agency] interpret[s] the relevant statute' is a final agency action." *Id.* (alterations in original) (quoting *U.S. Army Corps. of Eng'rs v. Hawkes Co.*, 578 U.S. 590, 599-600 (2016)). Consistent with the Fourth Circuit's recognition that Genesis' claims are a challenge to HRSA's final action in issuing the 1996 Guidelines, this case should be dismissed as untimely under the six-year statute of limitations.

II. GENESIS' "PATIENT" DEFINITION IS FUNDAMENTALLY CONTRARY TO THE PLAIN LANGUAGE, STRUCTURE, AND PURPOSE OF THE STATUTE.

On the merits, Genesis' atextual definition of "patient" is fundamentally inconsistent with the plain language, structure, and purpose of the 340B statute. Genesis' position is fatally inconsistent with the statute because (1) it fails to require **any** connection between a "covered entity" and a patient "with respect to" the "covered outpatient drug," and (2) it requires no **current** relationship between the covered entity and the purported "patient." Genesis' unlawful "definition" of a patient is utterly devoid of any limits. *E.g.*, Genesis SJ at 2.

A. Genesis' Definition of a "Patient" Fails to Require Any Meaningful Connection between a Recipient of a Discounted Drug and Either that Drug or the Covered Entity.

"'As with any question of statutory interpretation, [this Court's] analysis [must begin] with the plain language of the statute.'" *In re Wright*, 826 F.3d 774, 779 (4th Cir. 2016) (quoting *Jimenez v. Quarterman*, 555 U.S. 113, 118 (2009)). In doing so, the Court "must also 'read the words in their context and with a view to their place in the overall statutory scheme.'" *Id.* at 781 (quoting *King v. Burwell*, 576 U.S. 473, 486 (2015)). Here, the plain language of the diversion prohibition and its purpose foreclose Genesis' formless "definition" of the key term "patient."

The prohibition against diversion is a central component of the careful balance reflected in the 340B statute. It requires both that (i) a claimed covered drug must relate to the care provided by the covered entity to the patient and (ii) the patient is currently receiving care from the covered entity. The statute provides:

> With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity.

42 U.S.C. § 256b(a)(5)(B). Genesis' proffered "definition" fails to comport with both of these components of the statute's prohibitions.

The plain language of the statute, in forbidding any "transfer" of a covered drug to any "person" other than a "patient" of the covered entity, states that the statutory test must be satisfied "[w]ith respect to any covered outpatient drug." *Id.* § 256b(a)(5)(B). Thus, a "covered entity" may only transfer a "covered outpatient drug" to a person who is "patient of the entity" "[w]ith respect to" the "covered outpatient drug." *Id.* In other words, the covered entity must transfer the covered drug to a patient with whom the covered entity has a relationship "[w]ith respect to" that drug. *Id*. The text of the statute reinforces this very point in specifying what drugs are included in the key term "covered drug." Under, subsection (b)(2)(B), a "covered drug" includes "a drug used ***in connection with*** an . . . ***outpatient service provided by*** a hospital covered drug." *Id*. § 256b(b)(2)(B) (emphasis added). In keeping with the "with respect to" language, this text confirms (quite literally) the importance of a "connection with" an actual "service" that must be "provided" to the patient who "uses" the drug.

Moreover, Congress' choice of the word "patient" underscores the necessity of a connection between the services provided by the covered entity and the patient receiving the "covered drug." Dictionary definitions of the term "patient" define that word consistently in

relation to the specific care that the provider actually provides. The *Oxford Modern English Dictionary*, for example, defines the word "patient" in terms of the "medical treatment" provided or for which the person is "registered." *Id*. at 783 (1992) ("a person receiving or registered to receive medical treatment"). *Stedman's Medical Dictionary* defines a "patient," not merely as "one who is suffering from a disease or behavioral disorder," but who is specifically "***under treatment*** for ***it***." *Id.* at 1313-14 (26th ed. 1995) (emphasis added). *Merriam-Webster's Collegiate Dictionary* states that a "patient" is "the recipient of any [one or more] ***personal services***." *Id.* at 908 (11th ed. 2003) (emphasis added). Likewise, *Oxford Advanced Learner's Dictionary of Current English* makes the point quite directly. After defining "patient" based on the receipt of "medical treatment," it observes that patients are described in terms not only of the medical treatment received, but the underlying disease or condition for which the treatment is provided. *Id.* at 1133 (10th ed. 2020) (referring to "*cancer/AIDS/heart patients*"). *Stedman's Medical Dictionary for the Health Professions and Nursing* specifically defines a "patient" in terms of the relationship between the disease or condition and the "related" treatment. *Id.* at 1259 (7th ed. 2012) ("One who is suffering from disease, injury, an abnormal state, or a mental disorder, ***and is engaged in related treatment***.") (emphasis added).[14]

At its core, Genesis' argues that a covered entity should be able to claim a "patient" relationship where no such relationship exists or, indeed, ever existed in any way relevant either

[14] Multiple other definitions are to the same effect. In *Dorland's Illustrated Medical Dictionary*, for example, a "patient" is not merely a "person who is ill" or even one "undergoing treatment," but such a person where that treatment is "for disease," meaning the specific disease generating the illness and necessitating the treatment. *Id*. at 1245 (28th ed. 1994). Similarly, *Merriam-Webster's Medical Desk Dictionary* defines "patient" as a "client for medical service," where the "patient" is only recognized in relation to the provision of a "medical service." *Id*. at 522 (1993). Many similar definitions can be cited. *See, e.g., Webster's Third New Int'l Dictionary* at 1655 (1993).

(i) to the applicable disease or condition or (ii) to the use of the covered drug. Genesis SJ at 2 (arguing that 340B does not require that "the prescription being filled" originate with the covered entity). For Genesis, it would be perfectly appropriate for a clinic or hospital that treats a hip fracture to claim that its orthopedic patient is also its patient for wholly unrelated and distinct cardiology, neurology, or infectious disease conditions. But that is nonsense. No speaker of standard English would refer to a heart failure, multiple sclerosis, or communicable disease patient as the "patient" of an orthopedist. In such circumstances, the person receiving a drug is not a patient of the orthopedist "with respect to" the cardiology, neurology and infectious disease conditions or the drugs used to treat those conditions; there is no "connection" to the "service" "provided" by the orthopedist. 42 U.S.C. § 256b(a)(5)(B), (b)(2)(B); *see also Stedman's Medical Dictionary for the Health Professions and Nursing* at 1259 (defining a "patient" in terms of his or her own "related treatment").

The applicable legislative history reinforces this important connection between the term "patient" and the provision of care for a given condition. Thus, the legislative history tellingly limits the intended scope of 340B discounts to those safety net providers that provide "direct clinical care" to patients. House Report at 12. But, contrary to this legislative intent, Genesis' "patient" definition requires no relevant "direct" (or even indirect) "clinical care" by a covered entity to the person to whom it transfers a 340B drug. Under Genesis' "definition," the covered entity need not ever have (i) provided "direct clinical care" to the patient for the relevant condition, (ii) prescribed the relevant drug as part of its "direct clinical care" of the person, or (iii) dispensed that drug as a component of its provision of "direct clinical care." Indeed, under Genesis' "definition," it can claim a 340B drug discount even where it **knows** that some altogether distinct and separate provider is responsible for that patient, for that condition, and that drug therapy. *See*

Genesis SJ at 2. For Genesis, the 340B program is nothing more than a means to extract windfall profits where it has provided no care.

B. Genesis' Definition Also Fails to Require Any Current Patient Relationship, as Mandated by the Statute.

Perhaps even more fundamentally, Genesis' "definition" of a "patient" cannot be squared with the statute because Genesis refuses to recognize that the plain language of 340B mandates that a qualifying patient relationship exist currently whenever a drug is claimed for a discount.

Although Genesis is loath to highlight this aspect of its own policy, it does not even require that the "patient" be currently a Genesis patient — for any purpose — when it seeks a windfall from the 340B program. Gov't Br. at 9 (stating that Genesis claimed that individuals were "patients" even though they had not been seen by Genesis, for any service, up to two years before a drug was distributed). But the 340B statute requires that, at the time of any compliant "transfer" of any covered drug, the person receiving the drug "is" a patient of the entity. 42 U.S.C. § 256b(a)(5)(B) ("[A] covered entity shall not . . . transfer the drug to a person who ***is*** not a patient of the entity") (emphasis added). Genesis rewrites the statute, requiring only some **past** connection to the patient occurring "in the past 24 months." Genesis SJ at 9. Congress, however, specifically choose the present tense in defining the specific connection that must exist between the covered entity and the patient so as to prevent diversion of 340B drugs.

Dictionary definitions reinforce that a "patient" is a person who **is currently** receiving care. *See, e.g.*, *Random House Webster's College Dictionary*, at 990 (1991) ("who ***is*** under medical care") (emphasis added), *Stedman's Medical Dictionary for the Health Professions and Nursing*, at 1259 ("***is engaged*** in related treatment") (emphasis added); *Dorland's Illustrated Medical Dictionary*, at 1398 (32d ed. 2012) ("who ***is undergoing*** treatment") (emphasis added); *Collins English Dictionary*, https://www.collinsdictionary.com/us/dictionary/english/patient ("who ***is***

receiving medical care") (emphasis added); *American Heritage Dictionary*, at 1292 (5th ed. 2011) ("[o]ne who ***receives*** medical attention") (emphasis added); *Oxford Advanced Learner's Dictionary of Current English*, at 1128 (9th ed. 2015) ("who ***is receiving*** medical treatment") (emphasis added).

Although Genesis claims that it only seeks to claim 340B discounts for drugs for which the person receiving that drug "***is*** a Genesis patient," Genesis SJ at 3 (emphasis added), the administrative record shows that Genesis has claimed 340B discounts for drugs for persons who are not current patients. As the government notes, Brief at 9, Genesis purports to identify a "patient" by "using a two year lookback window" that searches for "**any** visits with a Genesis provider"—no matter how unrelated they may be to the drug at issue. *Id*. (emphasis in original). The use of that "lookback period" is an admission that Genesis is claiming 340B discounts for drugs for persons who are not current patients. This, in and of itself, is fatal to Genesis' claim.[15]

III. GENESIS' "DEFINITION" OF A PATIENT ALSO SHOULD BE REJECTED BECAUSE ITS UTTER LACK OF CONTENT LEADS TO ABSURD RESULTS.

Adoption of Genesis' atextual misreading of "patient" would—and does—produce absurd results. As a consequence, Genesis' "definition" would render the diversion prohibition a nullity and would only further impair the program.

When courts interpret statutes, they seek a "sensible construction that avoids . . . an absurd conclusion." *United States v. Granderson*, 511 U.S. 39, 56 (1994) (internal quotations and citation

[15] Genesis notes, Genesis SJ at 9, that, at one time HRSA suggested, in guidance, that a covered entity could consider whether an individual "has received at least one service in the past 24 months." But HRSA cannot deviate from the plain language of the statute, and the plain language requires a current, not a former, relationship between the "patient" and covered entity. Past services denote only a past relationship. And, indeed, Genesis' claim here is not even limited to situations where care related to the drug was provided two years ago. Genesis' position ultimately would require manufacturers to pay discounts no matter how many years had passed between the last unrelated service and the date the drug is dispensed.

omitted); *see also In re Jones*, 591 F.3d 308 n.4 (4th Cir. 2010) (explaining that courts avoid constructions of statutory language that would "'result[] in an outcome that can truly be characterized as absurd'") (quoting *Hillman v. IRS*, 250 F.3d 228, 233 (4th Cir. 2001)). Likewise, courts avoid "an interpretation of a congressional enactment which renders superfluous another portion of that same law." *Mackey v. Lanier Collection Agency & Serv., Inc.*, 486 U.S. 825, 837 (1988). Indeed, as the Fourth Circuit has explained, "it is well-settled that 'courts should disfavor interpretations of statutes that render language superfluous.'" *In re Wright*, 826 F.3d at 781 (quoting *Connecticut Nat'l Bank v. Germain*, 503 U.S. 249, 253 (1992)).

Genesis' essential position—that it should be able to "claim" profits for prescriptions for persons who it only saw years ago and only for conditions completely unrelated to the prescriptions at issue—has and would produce absurd results. Patients often have multiple conditions, and, just as often, they seek medical attention for those distinct conditions from multiple, distinct providers.[16] This is true at any given point in time, but patients often switch providers over time.[17] But under Genesis' virtually unlimited claims to a "patient" relationship, Genesis can profit from prescriptions from patients it never saw for the underlying condition, never prescribed the drug therapy, never dispensed the prescribed medication, and for which it even **knows** that another provider is responsible for the drug and related treatment. It does not matter, under Genesis'

[16] *See* Regina M. Benjamin, *Multiple Chronic Conditions: A Public Health Challenge*, 125 Pub. Health Rep. 626, 626 (2010) ("[A]lmost one in four Americans … have *multiple* chronic conditions," and "[i]t is not uncommon … for … patients [to have] five, six, or even seven chronic conditions."); *Id*. ("[O]lder adults with five or more chronic illnesses … on average … see 14 different physicians … per year.")

[17] *See* Sarah Sinha & Loren McCaghy, Accenture, *Healthcare Experience: The Difference Between Loyalty and Leaving*, at 3 (2022), https://www.accenture.com/content/dam/accenture/final/industry/health/document/Accenture-Humanizing-Healthcare-Experience-Payer-Provider-Health-PoV.pdf ("Nearly one-third" of surveyed patients selected "a new provider in 2021—up from 26% in 2017").

"definition" that Genesis has even not seen that patient—for any reason—for years. That "definition" is devoid of content and leads to absurd results.

Nor is this a "theoretical" concern, as demonstrated by data Janssen has recently collected from covered entities. For years, covered entities, like Genesis, have abused "contract pharmacy relationships" to claim discounts for drugs dispensed typically by large, for-profit retail pharmacies, often located hundreds or even thousands of miles away from the covered entity. As a result, Janssen and other manufacturers implemented policies that sought to secure data from covered entities using "contract pharmacies" and claiming 340B discounts. Janssen and other manufacturers only reluctantly took that step after years of oversight neglect by HRSA.

Although Janssen's program has only been operative since May 2, 2022, it has already revealed many claims where two **different** 340B covered entities have claimed (and been paid) 340B discounts on the **same** prescription for the **same** drug for the **same** "patient."[18] Importantly, contract pharmacies affiliated with the same large, for profit commercial pharmacies used by Genesis have been implicated in this diversion when acting in concert with other covered entities.[19]

With more than 13,000 covered entities and more than 30,000 contract pharmacies participating in the 340B program, the potential for multiple entities claiming discounts on the very same drug dispensed to the very same person is all too evident, if Genesis' patient "definition" were permitted. An analysis of active 340B covered entities in the HRSA OPAIS database

[18] At the most recent conference sponsored by 340B Health, the leading trade association for covered entities, an attorney from Powers Pyles, the Washington D.C. law firm most closely associated with that lobbying group, indicated that more than one covered entity claiming the same drug for the same patient was an issue that he and his law firm colleagues regularly address in drafting 340B agreements for clients. Remarks of Mark Ogunsusi, Esq., 340B Coalition Summer Conference (July 11, 2023).

[19] Janssen has not currently applied this policy to covered entities that are not hospitals, but are instead federal grantees, like Genesis.

indicates that there are **21** covered entities within 30 miles of a Genesis location and that **12** of those covered entities are within **3** miles of a Genesis location.[20] Under Genesis' atextual misreading of the statute, all of these covered entities (and many others) could claim profits on each prescription filled for each "patient," even if none of those covered entities was currently providing care to the individual, never treated the individual for the condition relevant to the prescription, never issued the prescription to the individual, and never dispensed the medication to the individual.

That result is not only absurd, but it effectively renders the statutory prohibition on diversion a nullity. Congress, in articulating a balanced program, made the diversion prohibition a core element of that balance. It emphasized the critical importance of that prohibition by authorizing HRSA and manufacturer audits to detect violations and providing for covered entity penalties for violations. *See* 42 U.S.C. § 256b(a)(5)(C) (obligating covered entity to submit to audits by "the Secretary and the manufacturer of a covered outpatient drug"); *id.* § 256b(a)(5)(D) (setting forth penalties for covered entities that violate restrictions in 340B program). But Genesis seeks, with its formless "definition," to all but read those provisions, reflected in the structure of the statute, out of the statutory scheme.

[20] These figures exclude other Genesis sites that are within 30 miles of a Genesis location, and reflect only active covered entity sites, not sites that have been terminated. These figures also do not include any contract pharmacies. Including the contract pharmacies located near these Genesis and other covered entity sites would substantially increase the points at which duplicate discounts could be claimed by all of these covered entities under Genesis' patient "definition."

CONCLUSION

For these reasons, Defendants' motion for summary judgment should be granted.

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Respectfully submitted,
/s/ Joel H. Smith

Joel H. Smith
Bowman and Brooke LLP
1441 Main Street,
Suite 1200
Columbia, SC 29201-2897
Telephone: (803) 726-74220
Facsimile: (803) 726-7421
joel.smith@bowmanandbrooke.com

Counsel for The Janssen Pharmaceutical Companies

William A. Sarraille (D.C. Bar No. 431872)
Pro hac vice motion pending
Paul J. Zidlicky (D.C. Bar No. 450196)
Pro hac vice motion pending
Sidley Austin LLP
1501 K Street, N.W.
Washington, D.C. 20005
Telephone: (202) 736-8000
Facsimile: (202) 736-8711
wsarraille@sidley.com
pzidlicky@sidley.com

CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the page requirements of Local Rule and 7.05(B) and uses 12-point Times New Roman font in accordance with Local Rule 1.05.

Dated: August 4, 2023

/s/ Joel. H. Smith
Joel H. Smith

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing will be served this 4th day of August, 2023, electronically through the Court's CM/ECF system on all registered counsel.

/s/ Joel H. Smith
Joel H. Smith